

## Fluzone® High-Dose Influenza Vaccine Question and Answer Document Updated – August 2019

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### 1. What is high dose inactivated influenza vaccine and how is it different from other influenza vaccines?

High dose trivalent inactivated influenza vaccine (HD TIIV) or Fluzone® High-Dose is an unadjuvanted vaccine that contains a higher antigen content per dose than standard dose (SD) TIIV formulations. HD TIIV contains 60 µg of hemagglutinin (HA) protein for each of the three vaccine strains (180 µg in total) compared to 15 µg of HA per strain (45 µg in total) in SD TIIV. Both HD and SD TIIV are delivered by intramuscular (IM) injection in a 0.5 mL volume per dose. HD TIIV comes in a 0.5 mL pre-filled syringe.

### 2. For whom is this vaccine indicated?

Fluzone® High-Dose is approved for use in Canada for adults 65 years of age and older.

### **3. What is the safety profile of high dose inactivated influenza vaccine?**

In some studies, HD TIIV has been associated with a higher rate of injection site (e.g., pain, induration) and systemic reactions (e.g., malaise, myalgia, fever) in the 7 days following vaccination than SD TIIV, but these adverse events were typically mild and short-lived with most resolving within three days. Serious adverse events (SAEs) were rare, and similar in frequency to SD TIIV. However, studies to date were likely under-powered to detect rare SAEs, such as Guillain-Barré Syndrome. Post-marketing surveillance of vaccine safety remains an important process to which all vaccine providers are expected to contribute.

### **4. What is the current National Advisory Committee on Immunization (NACI) recommendation for use of HD TIIV in provincial immunization programs?**

In its Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2019-2020, NACI recommends that provincial influenza vaccine programs may use any of the four influenza vaccines available for use in adults aged 65 years and older: standard dose TIIV, high dose TIIV, adjuvanted TIIV and QIIV (quadrivalent inactivated influenza vaccine). Because NACI did not review health economic data or other measures of the population impact or implications, it could not make a recommendation about preferential use of any of these products for public health programs.

In the same chapter, NACI recommends that at an individual level, the high dose TIIV should be offered over standard dose TIIV to persons 65 years and older because of the expectation of higher effectiveness.

A separate analysis of the available HD TIIV data in BC, concluded that while there are preliminary indications that adults 65 years of age and older may be relatively better protected by HD TIIV, additional studies are needed to confirm enhanced benefits that are consistent across seasons and vaccine strains, and especially among adults over 75 or 85 years of age who are most vulnerable to the severe complications of influenza. Furthermore, other considerations not taken into account by NACI, such as absolute impact and incremental cost-effectiveness, also apply in determining whether a particular vaccine product warrants preferential recommendation and public funding over other available options.

### **5. What is the current Advisory Committee on Immunization Practice (ACIP) recommendation for use of HD TIIV in the United States?**

The US Advisory Committee on Immunization Practices has not recommended preferential use of any particular influenza vaccine for elderly adults 65 years of age and older. HD TIIV has been approved for use in the US since 2009.

## 6. Why is HD TIV not publicly funded in BC?

In addition to approval by Health Canada and a recommendation for use based on available scientific evidence by NACI, other factors are also relevant for provinces to consider when deciding whether a vaccine product should be preferentially funded over other available options. This includes consideration not only of relative protection but also absolute reduction in disease burden, the numbers needed to vaccinate to achieve that, the relative costs and incremental cost effectiveness, as well as feasibility and logistics of implementation.

The BC Communicable Disease Policy Advisory Committee has reviewed the information currently available on HD TIV. For instance, the committee considered that in the pivotal trial of HD TIV efficacy compared to standard dose TIV, HD-TIV reduced the risk of influenza by 24% based on a risk of developing influenza of 1.9% in those who received the standard formulation compared to 1.4% in community living seniors who received the high dose product. Based on this finding from a single influenza season, an additional 200 such individuals would need to be immunized with the high dose product to prevent 1 additional case of influenza, and 4000 to prevent one additional hospitalization within 30 days of specified illness.

The Committee concluded that the strength of the evidence and anticipated incremental benefit of high dose TIV relative to standard dose TIV is not commensurate with the additional 5-fold cost and provided its recommendation to the Ministry of Health. The Ministry weighs available evidence, advice and other considerations in making the final decision on whether to fund a particular vaccine program. While NACI has concluded that based on available evidence, high dose TIV should provide superior protection compared to standard dose TIV for adults 65 years of age and older, this is based on the limited information available to date. Studies in other jurisdictions are being conducted to compare the performance of the high dose vaccine to other influenza vaccines in additional seasons and settings, and these will inform future decisions about incorporation of the high dose vaccine into population based programs.

## 7. Is HD TIV publicly funded in other Canadian jurisdictions?

For the 2019-2020 season, Ontario is the only jurisdiction where the vaccine is being provided to all seniors as part of the publicly funded influenza vaccine program. In some Canadian jurisdictions high dose TIV is being provided to residents of long term care facilities.

## 8. What is my professional responsibility to tell clients/patients that this product is an alternative to publicly funded influenza vaccine?

It is important to recommend influenza vaccine to your patients who are 65 years of age and older to protect them from the serious complications of influenza.

However, there are several influenza vaccines on the Canadian market in any given season, and not all are provided in every jurisdiction or through publicly funded programs. The current offering of influenza vaccine in British Columbia for seniors is in keeping with national recommendations,

Canadian provincial/ territorial programs, as well as immunization programs in many high income countries.

With knowledge of a specific patient's risk factors for severe illness due to influenza, providers may choose to inform clients of the availability of high dose TIIV.

## **9. Where can I obtain more information on HD TIIV?**

The following sources of information are available online:

- NACI [Statement on Seasonal Influenza Vaccine for 2019–2020](#)
- Sanofi Pasteur [product monograph](#)
- Sanofi Pasteur [Fluzone® High-Dose](#) page

## **10. Where can members of the public access high dose influenza vaccine?**

HD TIIV will be available through many pharmacies throughout BC.